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ID

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/289,180	04/09/99	SHIMOKAWATOKO	Y 2185-0324P-S

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HM22/0118

EXAMINER

TUNG, P

ART UNIT	PAPER NUMBER
1652	12

DATE MAILED: 01/18/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/289,180

Applicant(s)

Shimokawatoko et al.

Examiner

Peter Tung

Group Art Unit

1652



☐ Responsive to communication(s) filed on _____.

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 8-34 is/are pending in the application.

Of the above, claim(s) 8-27 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 28-34 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

1. Claims 8-34 are pending.
2. Claims 8-27 are withdrawn from further consideration as being drawn to a non-elected invention.

Election/Restriction

3. Applicant's election with traverse of Group I, claims 1-7, in Paper No. 11 is acknowledged. The traversal is on the ground(s) that there is no undue burden in searching for all claims and that Groups II and III are members of the same subclass. This is not found persuasive because undue burden would be required to search the non-patent literature for both Groups II and III.

The requirement is still deemed proper and is therefore made FINAL.

Specification

4. The use of the trademarks "Marathon" cDNA amplification kit, page 19, line 12; "DIG-High Prime DNA Labeling and Detection Starter Kit I," page 22, line 7-8; "MicroSpin S-400HR," page 34, line 13, among others, has been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology.

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Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 28-34 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection was explained in the previous Office action.

7. Applicants argue that the instant claims are drawn to a method of using the PPO gene and not to claiming the gene itself. Applicants argue that the structures of the PPO genes are well known in the art.

8. Applicant's arguments filed 11/3/00 have been fully considered but they are not persuasive. As the instant claims are drawn to a method of using a PPO gene, adequate description of the PPO gene is required. No evidence has been provided to indicate that the complete structure of the PPO gene has been described, i.e., include intervening, regulatory, promoter and terminator sequences. It is noted that this rejection may be overcome by replacing "gene" with "DNA."

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9. Claim 28-34 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The breadth of the claims encompass any host cell deficient in growing ability to be transformed with a vector encoding a PPO. However, inadequate guidance and examples are provided for the claimed method using any host cell deficient in growing ability. As the invention is a method of determining inhibition of PPO activity, the use of any host cell deficient in growing ability would not work. The skill of those in the art is low in determining inhibition of PPO activity using any host cell deficient in growing ability. Undue experimentation would be required to determine inhibition of PPO activity using any host cell deficient in growing ability.

10. Claim 33 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Adequate description for the species encompassed by the claim would have

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relevant identifying characteristics which include 1) structure, 2) physical and/or chemical characteristics, 3) functional characteristics when coupled with a known or disclosed correlation between function and structure, 4) a combination of these. The instant claim is drawn to a method using a protoporphyrinogen oxidase gene derived from specific animals and plants. As PPO genes from those sources are not disclosed and no known correlation between function and structure for PPO genes is known, there is inadequate description for the claimed PPO genes.

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 29, 31, 33 and 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

13. Claims 29 and 31 are unclear as what is meant by "... a terminator functionable in the host cell ..." It is also unclear how the "terminator" is related to the other described components of the system and what its function is.

14. Regarding claim 33, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

15. Claim 34 is indefinite because it depends upon an indefinite base claim and fails to correct the problem.

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Conclusion

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter Tung, Ph.D. whose telephone number is (703) 308-9436. The examiner can normally be reached on Monday-Friday from 9:00 to 5:30.

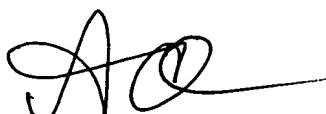
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, Ph.D., can be reached on (703) 308-3804. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-0294.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



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